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Publication Title:

A spectrophotometric metabolism monitoring apparatus

Abstract:

Abstract of GB2135074

A mounting structure secures to a selected portion of the human body, e.g., the head, and incorporates light source and light detecting means adapted for association with spectrophotometric circuitry for in situ, in vivo monitoring of local metabolism or another selected body activity in the area of the body where the structure is secured. Data supplied from the esp@cenet database - Worldwide

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(54) **A spectrophotometric metabolism monitoring apparatus**

(57) A mounting structure secures to a selected portion of the human body, e.g., the head, and incorporates light source and light detecting means adapted for association with spectrophotometric circuitry for in situ, in vivo monitoring of local metabolism or another selected body activity in the area of the body where the structure is secured.

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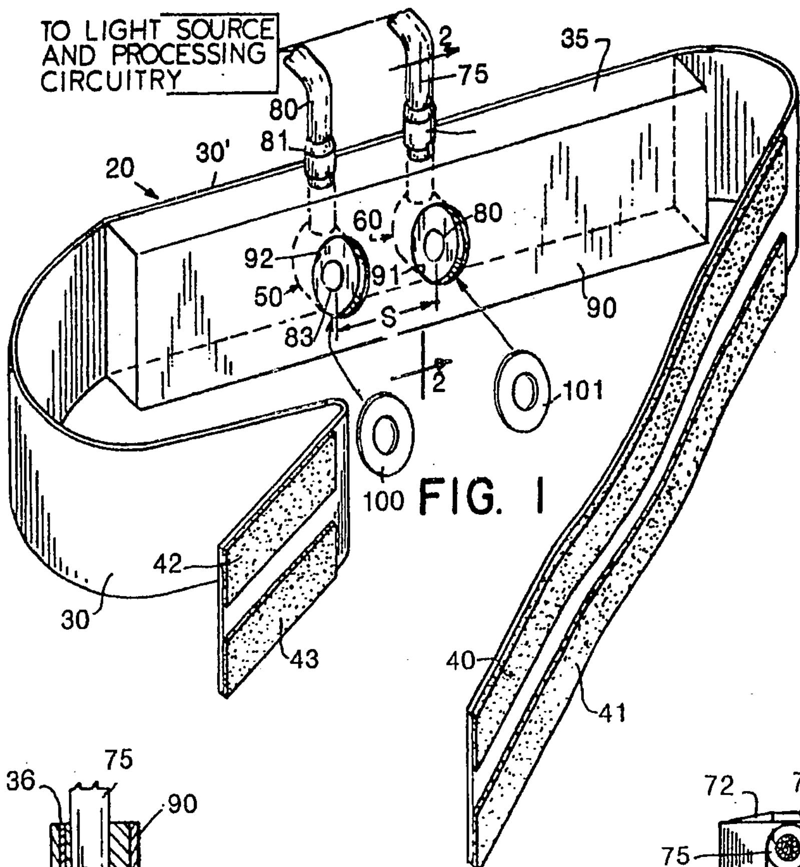


FIG. 1

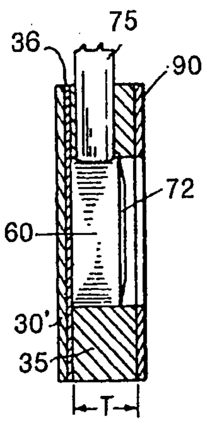


FIG. 2

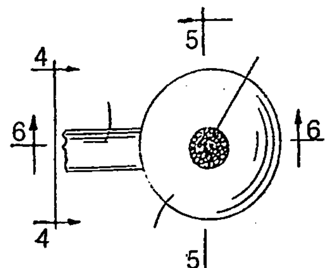


FIG. 3

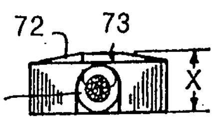


FIG. 4

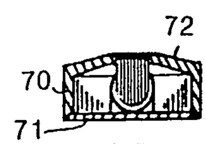


FIG. 5

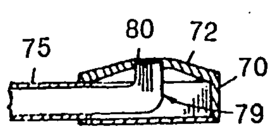


FIG. 6

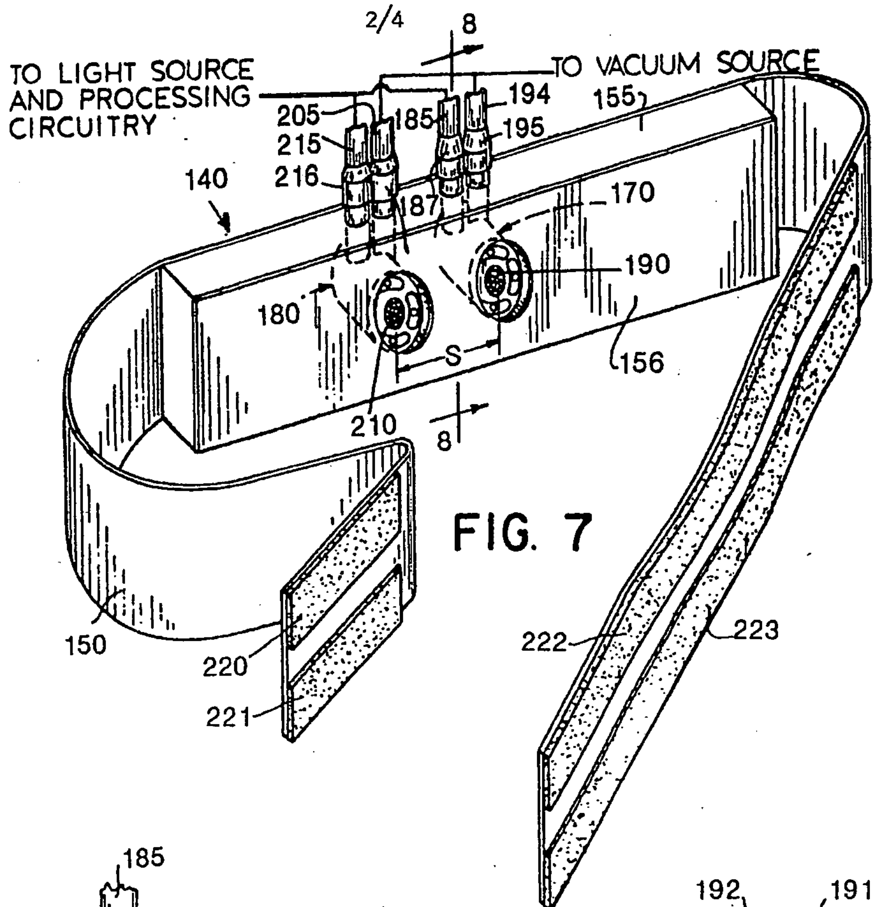


FIG. 7

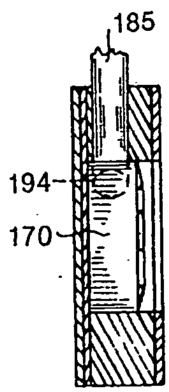


FIG. 8

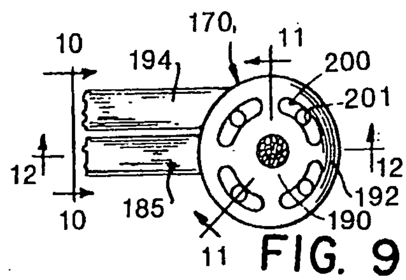


FIG. 9

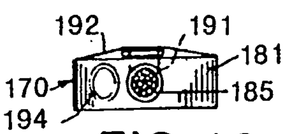
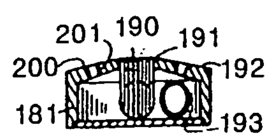


FIG. 10



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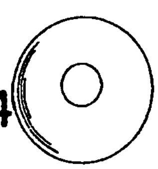

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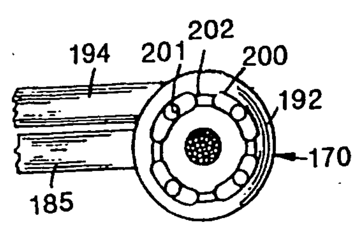


FIG. 13

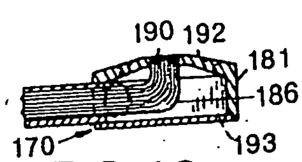


FIG. 12

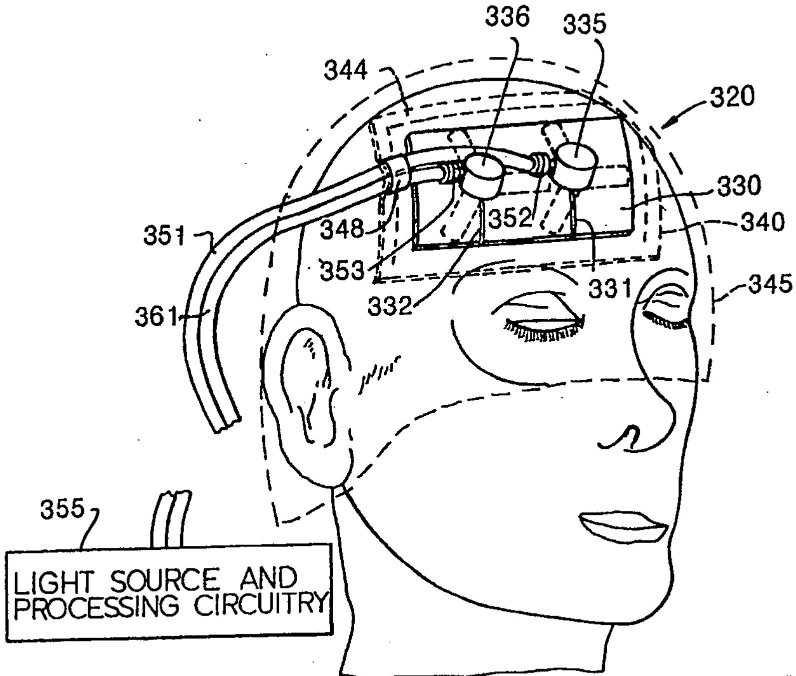


FIG. 15

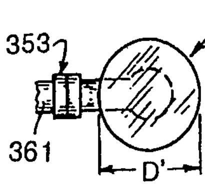
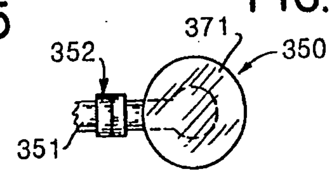


FIG. 16

FIG. 19



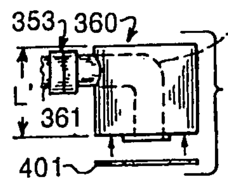


FIG. 17

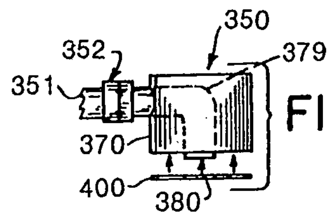
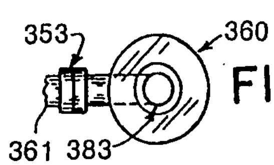


FIG. 20



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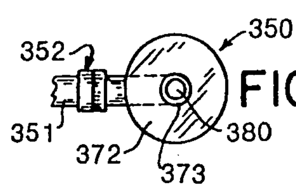

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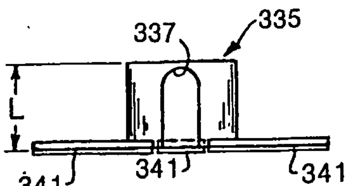

FIG. 22

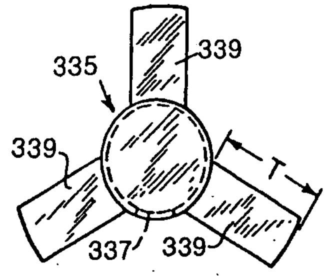

FIG. 23

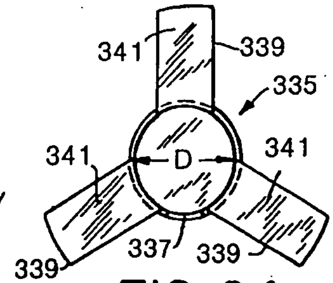

FIG. 24

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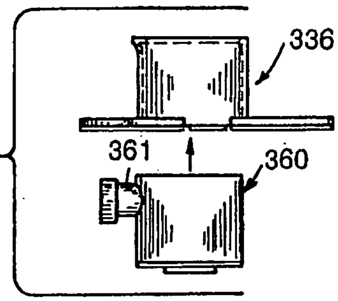

FIG. 25

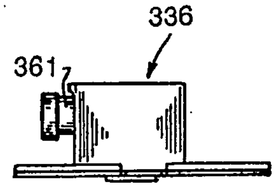

FIG. 26

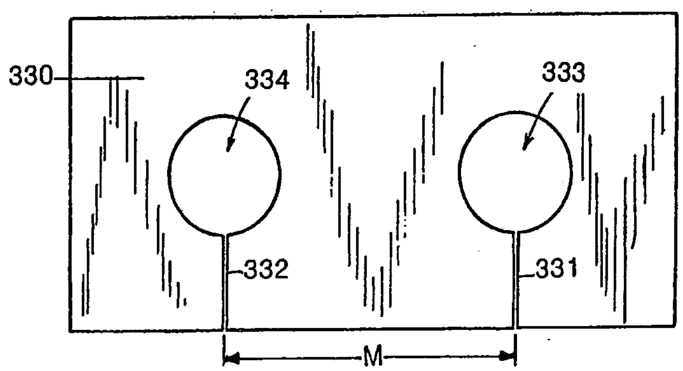

FIG. 27

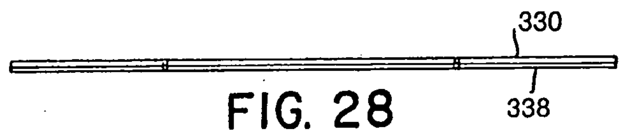

FIG. 28

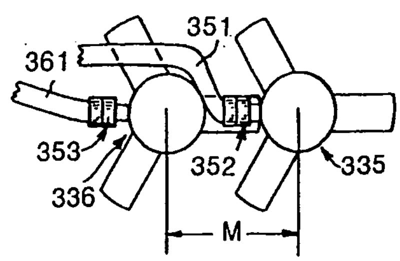

FIG. 29

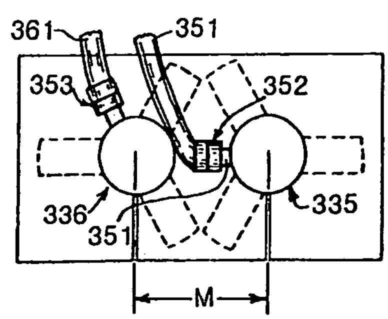

FIG. 30

SPECIFICATION

Metabolism monitoring apparatus

Technical Field

The invention relates to spectrophotometric apparatus for monitoring selected characteristics of the human body in vivo and more specifically to apparatus associated with the monitoring apparatus for mounting and providing light shielding for light source and light detector means on the body, particularly on the head of a living human patient.

Background Art

In prior United States Patents 4,223,680, 4,281,645 and 4,321,930, there has been described a spectrophotometric method and apparatus directed to noninvasive, continuous, atraumatic, in vivo, in situ monitoring of metabolism in a body organ. In the described applications set forth in these patents, measuring and reference wavelengths within the near-infrared region, i.e., 700–1300 nm, are utilized for non-invasive, continuous, atraumatic, in vivo, in situ monitoring of oxidative metabolism by monitoring oxygen sufficiency in an internal organ, e.g., the brain, of a human or animal body. Advantage is taken of the critical characteristic of cellular enzyme cytochrome *a*, a_3 (also known as cyctochrome *c* oxidase and identified by EC 1.9.3.1) within the optical path and within the radiated portion of the selected organ for absorbing the selected measuring wavelength and for light of this measuring wavelength, as well as at least one reference wavelength within the same defined infrared region and at a low, non-hazardous level of intensity to be detectable at the end of a relatively long transillumination or reflectance path, e.g., of several centimeters length, which may include substantial content of bone as well as soft tissue and skin. Variations in metabolic and circulatory parameters during measuring are recognized and the selection of wavelengths, circuitry and method also provide techniques for compensating for changes in blood volume in the organ being monitored, for continuous monitoring of hemoglobin oxygenation and blood volume, for intermittent monitoring of blood flow rate, for skin blood flow effects and variations in the light source, i.e., laser diode, output.

The prior art is discussed extensively in the mentioned prior patents and in the context of the prior patents and other prior art cited in the those patents, the present invention is primarily concerned with the light source and light detecting structure at the place of attachment to the body and with the means for mounting the light source-light detecting structure on the body. Thus, the present invention is primarily intended to provide an improvement over the light source-light detecting structure shown in the prior patents as well as over all known prior art deemed relevant to the invention. Other useful background may be had by making reference to the light source and light detecting structures described in United States Patents Nos. 3,527,932; 3,674,008; 3,638,640; 3,704,703; and 4,077,399.

Taking all of the foregoing into account, further development and experimentation with the spectrophotometric apparatus and method for measuring local metabolism described in the mentioned patents has revealed the need for an improved means for securing and shielding the light sources as well as the light detectors when attached to the body and particularly in reference to improving the light source-detector mounting arrangement described in United States Patent 4,321,930. Also, a need has arisen for further simplification of the light source-light detecting structure which is attached to the body and to the associated mounting structure such that it can be made economically in a disposable form and where necessary for a single end use application such as in a surgical operation, emergency accident situations, and the like.

A need has also arisen for an improved form of mounting in those medical and surgical procedures in which the patient is prone and the head of the patient is required to be tilted back, either for examining or introducing substances or instruments into the throat of the patient.

The achievement of these various needed improvements thus becomes the general object of the invention and other objects will be revealed as the description proceeds.

Disclosure of Invention

The invention is directed to improvements in means for orienting in reference to the body, supporting on and attaching to the body, and shielding from ambient light at the point of attachment the light sources and the light detectors associated with remotely located spectrophotometric apparatus utilized for measuring local metabolism in vivo, non-invasively and atraumatically according to the teachings of the related and previously mentioned prior patents.

The invention apparatus is attached to the body, e.g., the head, a limb, or to the torso, and operates with the apparatus and according to the techniques of the prior patents. Decisive information is provided on the parameter of oxygen sufficiently in the tissue or organ in question, in vivo. The invention apparatus, when operating in conjunction with the apparatus and techniques of the prior patents also provides the capability of monitoring the oxygenation state of the blood being supplied, blood volume and blood flow rate in the portion of the body being monitored and in a manner which is non-invasive

and atraumatic.

As distinct from the means for generating the near-infrared light sources, the timing, detecting and processing circuitry of the prior patents, the present invention is primarily concerned with improvements in the body-mounted light emitting and light detecting components and with improved means for detachably mounting, light shielding and orienting such light source-detecting components on the body and in a manner designed to avoid excessive localized pressure and erroneous signal conditions.

The body-mounted invention apparatus is utilized in association with the near-infrared sources, timing, detecting and processing circuitry as well as the measuring techniques described in the prior patents. Thus, by making reference to the subject matter of the prior patents, it will be understood that the present invention apparatus facilitates the carrying out of a continuous, non-invasive, in vivo, in situ monitoring of the redox state of cytochrome *a*, a_3 in the body portion of interest by using the deep, diffuse, multiple-scattered light, reflectance or transillumination technique and near-infrared radiation within the range of about 700-1300 nm as referred to and fully described in the prior patents. When the invention apparatus is applied to the head, for example, the light source and light detector components are spaced apart on the same side of the head and the light reflected and scattered back to the light source location is detected and used in the associated processing circuitry of the prior patents as a correction for skin blood volume changes. The present invention is particularly advantageous in minimizing light loss and also minimizing the establishment of localized pressure conditions and thus avoiding erroneous signal conditions. The present invention apparatus also further enhances the ability to discriminate between light scattered by the gray matter and light reflected from the white matter of the brain so as to provide a signal known to be indicative of the oxygen sufficiency in the grey matter of the brain.

With more specific reference to the actual structure employed in the improved light source-light detector body mounted apparatus of the invention, two embodiments are provided. There is provided in a first embodiment a strap designed to be wrapped around a selected portion of the body, e.g., around the head, a limb, or the torso, with the strap ends detachably secured for the purpose of supporting and orienting the light source, light detector, light shielding fiber optic and cable components of the invention. The mentioned strap mounts intermediate its length a block or section of resilient material adapted to conform to the shape of the body at the place of attachment. Such resilient material also serves as a means for encasing a pair of optical modules, the terminal ends of which serve as the required light source and light detector elements. These terminal ends are adapted to be detachably connected by quick disconnect couplings to a cable assembly used to transfer light or light related signals between the body-mounted apparatus of the invention and external apparatus providing the light sources, the timing, detecting and processing circuitry in which the desired spectrophotometric measurements are actually made according to the techniques of the prior patents.

As compared to the light source-detector assembly of United States Patent 4,321,930, both embodiments of the present invention provide an overall further simplified assembly. Additionally, improvements are provided by forming the light source and detector elements as uniquely constructed and separately mounted modules. The present invention also provides an improved means of light shielding obtained by using a double-sized, annular adhesive tape around the optical faces to improve both light shielding and body securement. Further, the first embodiment of the present invention provides the option of using a vacuum sealing arrangement in conjunction with a strap arrangement to further enhance securement of the light source-detector elements to the body and whether of the fiber optic or electronic type.

In the second embodiment, a strap is not required and the light source and light detector modules are mounted, light shielded, and accurately spaced by means of an adhesive pad arrangement. This is of particular significance in those medical and surgical procedures in which the patient is prone and the head of the patient is required to be tilted back, either for examining or introducing substances or instruments into the throat of the patient.

Both embodiments of the body-mounted invention apparatus provide means for detecting light reflected and scattered back from the location where the light first enters the body as well as separate means for detecting both scattered and reflected light at a point spaced from the light entry point. The invention apparatus also provides improved light shielding to prevent entry of ambient light or other extraneous light signals and also in a manner designed to avoid the establishment of harmful localized pressure at those points where the light enters and is detected. Thus, correction for skin blood volume changes is provided in all embodiments by means of monitoring the light reflected back at the point of light entry in conjunction with using the light reflected and scattered back to the second point for processing according to the techniques of the prior patents.

In both embodiments, the incoming light is transferred to the body-mounted apparatus of

the invention by means of an optical cable connected to the light source element of the body-mounted apparatus. The corrective light reflected back from the body at the point where light from the light source enters the body as well as the measuring light reflected and scattered back to a point spaced from the light source are both detected and transmitted for processing by optical fiber means. The reflectance technique utilized by the present invention should be construed as the deep reflectance technique fully described in prior United States Patent 4,321,930.

Description of the Drawings

Figure 1 is a pictorial view of the body mountable light source-light detector apparatus according to a first embodiment of the invention.

Figure 2 is an enlarged partial section view taken substantially along line 2–2 of Fig. 1.

Figure 3 is a plan view of an optical module suited to the apparatus of Fig. 1.

Figure 4 is an end view of the optical module of Fig. 3 taken in the direction of line 4–4 of Fig. 3.

Figure 5 is a section view taken substantially along line 5–5 of Fig. 3.

Figure 6 is a section view taken substantially along line 6–6 of Fig. 3.

Figure 7 is a pictorial view of the body mountable light source-light detector apparatus illustrating a modification of the first embodiment of the invention utilizing a vacuum attachment to the body.

Figure 8 is an enlarged partial section view taken substantially along line 8–8 of Fig. 7.

Figure 9 is a plan view of a vacuum adapted optical module suited to the apparatus of Fig. 7.

Figure 10 is an end view of the optical module of Fig. 9 taken in the direction of the line 10–10 of Fig. 9.

Figure 11 is a section view taken substantially along line 11–11 of Fig. 9.

Figure 12 is a section view taken substantially along line 12–12 of Fig. 9.

Figure 13 is a plan view of a modified vacuum adapted optical module suited to the apparatus of Fig. 7.

Figure 14 is a plan view of one side of an annular-shaped, double-sided, pressure sensitive tape useful with any of the optical modules of the invention.

Figure 15 is a pictorial view of the body mountable light source-light detector apparatus of the invention according to a second embodiment and illustrated as being mounted on the forehead of a patient for monitoring the brain.

Figure 16 is a top plan view of the light detector optical module used in the second embodiment.

Figure 17 is a side view of the light detector optical module shown in Fig. 16 and showing an annular light shielding pad used in conjunction with such module.

Figure 18 is a bottom view of the light detector optical module shown in Fig. 16.

Figure 19 is a top plan view of the light source optical module shown in Fig. 16.

Figure 20 is a side view of the light source optical module shown in Fig. 19 and showing an annular light shielding pad used in conjunction with such module.

Figure 21 is a bottom view of the light source module shown in Fig. 19.

Figure 22 is a side view of a module mounting socket of the type used in the second embodiment of the invention for receiving either a light source or light detector module and releasably securing the same to the body in spaced relation.

Figure 23 is a top view of the module socket shown in Fig. 22.

Figure 24 is a bottom view of the module socket shown in Fig. 22.

Figure 25 is an exploded side view illustrating how the light detector module of Fig. 17 is assembled in the module socket of Fig. 22.

Figure 26 is a side view of the light detector module of Fig. 22 fully nested in the module socket.

Figure 27 is a plan view of a light shielding pad used in the second embodiment of the invention and adapted to secure and shield both the light detector module and the light source module after being nested in their respective sockets with the socket tabs adhesively secured to the body in spaced relation.

Figure 28 is an elevation view of the pad shown in Fig. 27.

Figure 29 is a plan view in reduced size of the light detector and light source modules as shown in Figs. 16 and 19 assembled in their respective sockets and illustrating how the socket tabs may be used as a means for accurately spacing the optical modules apart.

Figure 30 is a plan view in reduced size of the light detector and light source modules as shown in Figs. 16 and 19 assembled in their respective sockets and illustrating how the optical module spacing may be determined by the pad construction of Fig. 27.

Best Mode for Carrying Out the Invention

With the background description provided by the prior patents, it becomes evident that when the deep reflectance technique is followed, as described in prior United States Patent 4,321,930, the means employed for introducing and implementing deep penetration of the near-infrared measuring and reference wavelengths at the point of light entry on the body, the means employed for collecting the directly and deeply reflected light at the point of light entry and the means for collecting the deeply penetrating light after being scattered and reflected from the organ, e.g., the brain or other body portions of

interest, are of crucial and significant importance to obtaining meaningful measurements of the parameters desired. It is desirable, for example, that the light source-light detector assembly which is attached to the body be in a form adaptable to various body shapes such as associated with the head, a limb, or torso of a human or animal subject under observation. It has also been found critically important that light shielding associated with the body-mounted light source-detector assembly be effective both as to extraneous near-infrared as well as extraneous ambient light such that the light entering the body as well as the light detected will be only those wavelengths and only from those light sources intended to be associated with the measurements. Extraneous photon energy at the measuring location which might otherwise enter the body and affect the measurements is therefore desirably absorbed by means associated with the light source-detector assembly of the invention.

It has also become increasingly evident that the light source-detector which attaches to the body must be in a form which avoids restricting local bloodflow or any other tissue function in the area of observation so as to avoid erroneous signals. Additionally, it has been found desirable that the light source-detector elements have an improved body mounting arrangement that not only lends itself to shielding of extraneous light but also protects the elements as the mounting assembly changes to conform to the body shape at the area of observation. Another critical feature in the light sorce-detector element mounting structure is that the relative space between the light source and detector elements remain fixed during the measuring period and not be subject to alterations by physical changes in body geometry brought about by breathing, flexing of the body, trauma, and the like. Another major consideration is that the light source-detector assembly which is mounted on the body be in a form adapted to be quickly coupled and uncoupled to the timing, light source, detecting and processing circuitry typically located at least several feet away from the patient.

As another important consideration, it has been found highly desirable that the light source-detector assembly which attaches to the body be in a form lending itself to economical manufacture so as to be adapted to a single end use and useful as a disposable component. Considering the difficulty and cost of washing and sterilization, the possibility of transmitting diseases and the likelihood of contamination in surgical and accident cases in particular, the advantage of having a prepacked, sterilized, single end use, disposable light source-detector assembly will be readily appreciated.

With the foregoing background information and desired characteristics and objectives in mind, the description next makes reference to the drawings to illustrate how the same are achieved in the improved, body-mounted light source-light detector assembly of the invention according to a first embodiment utilizing a strap arrangement. After completing the description of two forms of the first embodiment, the description will then proceed to a description of the second embodiment which utilizes light source and light detector modules generally of the same type as described in reference to the first embodiment but with a different securing means. After completing the description of two forms of the first embodiment, both of which use a strap-like arrangement but one of which uses a vacuum arrangement, the description will then proceed to describing the second embodiment based on using similar light source-light detector modules with an adhesive pad arrangement for mounting rather than a strap arrangement as in the first embodiment.

Referring initially and principally to Figs. 1–6, the improved light source-detector assembly 20 of the invention in a first embodiment basically comprises a base support strap 30, a module support 35 and embedded in support 35 a light source-detector module 50 and a light detector module 60.

Base support strap 30 is preferably formed of a tightly woven, elastic fabric such as found, for example, in elastic straps, stretchable belts, elastic fabric, and the like. Strap 30 should preferably have an ability to stretch while providing sufficient flexibility to conform to the shape of the head, limb or torso of a human or animal subject under investigation. All surfaces of strap 30 are preferably black in color to assist in absorbing extraneous photon energy proximate to the observation area. The body strapping and unstrapping operation utilizing strap 30 is facilitated by employment of mating "Velcro" type strips 40–43 on the corresponding mating surfaces of strap 30 such that strap 30 can easily conform to the size and shape of body contour where the light source-detector assembly 20 is attached for monitoring purposes as described in the prior patents.

Strap 30 includes an intermediate portion 30′ adhered to an outer side surface of what will be referred to as the module support 35. A double-sided pressure sensitive tape 36 is used for this purpose and provides a means for both positive securement and ease of removal of the module support 35 when necessary for purposes of replacement or service.

Module support 35 is preferably formed of a material which is both resilient and deformable to a degree suited to the invention as described. Foam, e.g., silicone rubber, represents a material which can be obtained with varying degrees of resiliency and is deemed

suited for this purpose. Module support 35 is molded preferably with preformed cavities, not shown, suited to lightly gripping and encasing the pair of optical modules 50, 60 which are supported by module support 35 on strap 30.

While serving different functions, optical modules 50 and 60 are basically of similar construction and will be described in reference to Figs. 2–6. Module 50, by way of example, comprises a hollow, circular-shaped housing 70 having a back cover plate 71 and a slightly tapered or slightly rounded front face 72 formed with a central aperture 73. A fiber bundle 75 couples through a quick disconnect optical coupling 76 and terminates with an L-shaped terminal end 79 having a ground optical face 80 located in the aperture 73. The void within housing 70 surrounding the L-shaped terminal end 79 is filled with an epoxy or similar hard setting compound to facilitate securement of the terminal end 79 within housing 70 and back cover plate 71 is suitably glued or otherwise secured in place after such assembly.

Terminal end 79 of fiber bundle 75 provides both a near-infrared light source terminal and a corrective detector terminal with selected fibers being employed for bringing light to the point of light entry and other randomly dispersed selected fibers being employed for collecting light reflected back directly from or near (1–3 mms) the point of light entry. The manner in which such corrective and measured light sources operate and are processed are fully explained in the previously referred to prior patents.

Module 60, as previously stated, employs a similar construction to that of module 50 and mounts a fiber bundle 80 through a quick disconnect optical coupling 81 having an L-shaped terminal end 82, not shown, with a ground optical face 83. Bundle 80 is used as a means for collecting the measured reflected light for processing as explained in the prior patents. During the light measuring operation, modules 50 and 60 are mounted in module support 35 and the invention assembly 20 operates so as to maintain uniform the spacing "S" within the limits discussed in the prior patents.

Shielding of ambient light is deemed important especially when metabolic trends are being monitored and discrete changes are significant though small in value. Such shielding is provided by employing a layer of light shielding material 90 adhered to module support 35 and formed with suitable holes 91, 92 as illustrated to avoid covering the respective optical faces 80, 83.

As another aspect of the present invention, a pair of double-sided, annular-shaped, pressure-sensitive, adhesive tapes 100, 101 are employed on the respective modules 50, 60 and used to assist in providing the desired ambient light shielding. Tapes 100, 101 are preformed in the shape illustrated in Fig. 14 and typically have removable adhesive protective covering which, after removal, allows the respective tapes 100, 101 to be attached one side to the respective modules 50, 60 while leaving the opposite side of the respective tapes 100, 101 exposed for securing to the respective body sufaces opposite the respective optical faces 80, 83.

In using the invention assembly 20, an optical gel is applied to each optical face 80, 83 and strap 30 is secured to the selected portion of the body so as to slightly compress the material forming module support 35 and bringing the respective optical faces 80, 83 with the respective surrounding annular tapes 100, 101 into firm engagement with the body surfaces to maximize light contact and minimize leakage and loss of light at the points of light entry and exit. The slightly tapered or rounded surfaces on the respective front faces, e.g., face 72 of module 50, have been found useful in some applications as a means for facilitating such contact in view of the substantial variations in contour and surfaces found on the human body. Once the strap assembly 20 of the invention has been properly secured as explained in the previously mentioned prior patents, appropriate optical and electrical circuits are established according to the prior patents and the present invention apparatus is used in the manner previously explained in such prior patents.

One of the important advantages of the improved strap assembly 20 of the present invention according to the first embodiment resides in the ability to preform the respective optical modules 50, 60 and assemble such optical modules with the module support 35 as a subassembly which can be quickly attached to the support strap 30 as previously explained and quickly coupled and uncoupled by means of the previously mentioned quick disconnect couplings 76, 81. Modules 50, 60 may be made of a suitable metal or plastic and molded or machined into the previously described form. Any suitable fabrication means may be employed to obtain the L-shaped configuration of the terminal ends of the respective optical bundles 75, 80 and to secure such optical bundles with respect to the respective optical modules 50, 60 so as to maintain the respective optical faces 80, 83 fixed relative to the respective modules 50, 60.

Referring next to Figs. 7–13, there is described another form of the first embodiment of generally the same construction as the form of the first embodiment previously described but with the addition of a vacuum arrangement to enhance light shielding and securement of the respective optical modules. As with the first form of the first embodiment, the assembly 140 of the second form of the

first embodiment employs a base support strap 150 and a module support 155 secured to strap 150 and having a layer of light shielding material 156 with suitable openings for light passage as with the first form of the first embodiment. Within module support 155, there is embedded a pair of preformed optical modules 170, 180 of generally similar construction and also generally constructed similar to the previously described modules 50 and 60 but adapted for vacuum securement to the body.

Using module 170 by way of example, the hollow housing 181 mounts a fiber bundle 185 having an L-shaped terminal end 186. Terminal end 186 is optically coupled through a quick disconnect optical coupling 187 and terminates with a ground optical face 190 ground flush with a central aperture 191 formed in the slightly rounded or tapered front face 192. Housing 181 is formed with an internal air-tight chamber by means of back cover plate 193 which is secured in place to prevent air leakage and also by means of appropriate sealing against air leaks around fiber bundle 185 and optical face 190. The internal air-tight chamber within housing 181 is coupled to an air tube 194 connected through a quick disconnect coupling 195 to a suitable vacuum source, not shown. Front face 192 of housing 181 is formed with four elliptical depressions 200 which communicate through corresponding holes 201 to the vacuum chamber within housing 181 to which the vacuum supply air tube 194 is connected. In a third form of the first embodiment shown in Fig. 13, the elliptical depressions 200 are interconnected by other depressions 202 to increase the total body surface exposed to the vacuum effect.

Module 180, in a similar manner and utilizing a generally similar construction, mounts an optical bundle 205 connected through coupling 206 and having an L-shaped terminal, not shown, with a optical face 210, Module 180 also mounts a vacuum support air tube 215 coupled through a quick disconnect coupling 216 to the same vacuum source supplying vacuum air tube 194.

Bundle 185 serves the same function as bundle 75 of the first form of the first embodiment and bundle 205 serves the same function as bundle 80 of the first form of the first embodiment.

In using the strap assembly 140 of the second form of the first embodiment, the required optical transmission and vacuum circuits are established and optical gel is applied to the respective optical faces 190, 210. The strap 150 is then suitably secured so as to place the respective housing front faces, e.g., faces 192, and respective optical faces 190, 210 in suitable body contact and also to place the respective vacuum supplied recesses 200 directly over and surrounding the body surfaces serving as points of light entry and exit. Where increased vacuum effect is desired because of the nature of the body surface to which the invention apparatus is being attached, the alternative module construction illustrated in Fig. 13 increases the vacuum effect and thereby increases the vaccum assisted securement to the body. Thus, in conjunction with the resilient pressing effect afforded by strap 150 and module support 155, there is provided an improved auxiliary vacuum assisted means for obtaining improved light shielding and securement of the strap assembly 140. As with the first form of the first embodiment, the resilient and deformable character of the material chosen for module support 155 allows the thickness of the module support 155, as viewed in Fig. 8, to contract when strap 150 is applied and suitably secured by use of the appropriate "Velcro" straps 220–223. With the optical module support 155 resiliently compressed in this fashion, with an optical gel applied to the respective optical faces 190, 210 and with the appropriate vacuum applied to the respective modules 170, 180, it can be seen that a substantially improved and effective optical coupling is secured. Further, as with the first form of the first embodiment, the optical modules 170, 180 can be prefabricated and installed in appropriate molded recesses in module support 155 as a subassembly for quick connection to the light source, light processing and vacuum equipment. Further, annular, double-sided, pressure-sensitive tapes, as previously described, may be employed around the respective optical faces to enhance securement when not using the vacuum. However, the vacuum securement is particularly advantageous when measuring wet surfaced portions of the body as for example in open heart surgery.

While not illustrated, it will also be appreciated that the illustrated optical modules may be formed with continuous fiber bundles leading to the light source and processing circuitry so as to avoid the use of the illustrated quick disconnect couplings.

Also to be recognized is that the described vacuum arrangement lends itself to use with optical modules fitted with a photo-detector, i.e., electronic type light sensors as in prior Patent 4,321,930. Thus, a new and versatile means of securement by vacuum is provided.

Another feature to be recognized in the illustrated embodiments as best seen in reference of Fig. 2 is that the thickness T of the module support material is purposely made larger than the overall thickness X (Fig. 4) of the optical modules. This allows the module support foam material 35 to effectively slide on the respective optical modules and be slightly compressed during application to the body and which assists in holding the respective modules properly positioned.

Having descibed in reference to Figs. 1–14 three forms of the first embodiment in which an elongated strap-type securing means is employed, the description refers next to the second embodiment as illustrated in Figs. 15–30 in which the optical module-socket type construction is retained but in a form not requiring use of a strap as the securing means.

As background for the description related to the second embodiment, it is noted that in some surgical procedures in which it is desirable to monitor oxygen sufficiency in the brain, the procedure requires that the patient's head be tilted backward for admitting various instruments or substances in the throat or such backward head tilting may simply be desired surgical or medical procedure. In other medical or surgical procedures where oxygen sufficiency in the brain is desirably monitored, the patient's head may not require tilting. Particularly when it is necessary that the patient's head be tilted backward, it has been found that the releaseable strap arrangement described in Figs. 1–14 has certain disadvantages and caution is required to see that the light source-detector assembly is not dislodged or mispositioned when the patient's head is tilted backward. However, at other times when the patient's head is not tilted backward, the strap securing arrangement of the first embodiment as in Figs. 1–14 has proven satisfactory. Thus, in the structure of the second embodiment of the present invention an improved light source-detector body mounting assembly has been provided in which all of the desired characteristics previously achieved in the first embodiment have been retained while at the same time providing an improved mounting assembly especially adapted for use on the head during monitoring of the brain and which adapts to the patient's head being either tilted backward or not as required by the medical or surgical procedure involved.

Light source and light detector modules are used in both the first and second embodiments. In the second embodiment there is provided for each light source and light detector module a socket device adapted to receive the module and by means of radially extending flexible tabs to be adhesively secured to the body at the place of attachment using double-sided adhesive tape. The length of the socket tabs allows the pair of sockets holding the respective light source-light detector modules to be accurately spaced apart as required for practicing the optical monitoring techniques of the prior patents. The improved mounting apparatus of the invention according to the second embodiment also provides for a flexible light shielding pad to be adhesively secured to the body so as to cover the socket tabs and allow the remaining portions of the sockets to protrude outwardly from the pad and the appropriate interconnected optical cables to lead from the pad to the light source and processing circuitry of the related prior patents. Once the optical modules and their respective sockets have been appropriately mounted and have been suitably covered by the mentioned light shielding pad, an additional somewhat larger second light shielding pad is placed over the first pad so as to cover both the first light shielding pad, the sockets and those portions of the optical cables leading from the respective optical modules in the sockets. The second light shielding pad is adhesively secured to the body at the pad's peripheral edges employing double-sided adhesive tape. As a final light shielding procedure, a flexible light impervious cape such as previously disclosed in reference to the first embodiment is placed over that portion of the patient's body on which the mentioned optical modules, sockets and light shielding pads have been mounted so as to further shield both the light sources and modules from ambient light.

With specific reference to Figs. 15–30, the improved light source-detector assembly 320 according to the second embodiment of the invention comprises a flexible, light shielding adhesively secured base support pad 330, a pair of module sockets 335, 336, a light source module 350, a light detector module 360, an auxiliary light shielding pad 340 and finally an overall light shielding drape 345.

Base support pad 330 is preferably formed of a tightly constructed non-elastic, black coated fabric such as found, for example, in black coated Naugahyde fabric used for automobile seats, upholstery, and the like, and should preferably provide sufficient flexibility to conform to the shape of the head or other part of the body of the human or animal subject being monitored. Additionally, all surfaces of pad 330 should preferably be black in colour to assist in absorbing the extraneous photon energy proximate to the observation area. Positive securement of pad 330 to the body surface is facilitated by employment of a suitable pressure sensitive adhesive 338 over the entire surface of pad 330 which is adhered to the body. A removable cover sheet over adhesive 338 is desirable.

The module sockets 335, 336 are preferably formed of a molded plastic material which is both resilient and deformable to a degree suited to the invention as described. Each module socket 335, 336 provides a hollow, resilient wall housing molded with an open base end and closed upper end so as to snugly receive a respective light source module 350 or light detector module 360. In a preferred form, the inner diameter D and inner length L of sockets 335, 336 are of standard size as are the outer diameter D′ and outer length L′ of modules 350, 360. As best illustrated in Figs. 15, 22, and 26, each

module socket 335, 336 will also be noted as having an open slot 337 for receiving the respective optical cables 351, 361 leading from the respective optical modules 350, 360. Each respective socket 335, 336 is thus assembled with a respective optical module 350 or 360 as illustrated by way of example in Figs. 25 and 26 with respect to the assembly of the socket 336 with the light detector module 360.

Optical cables 351, 361 made up of bundles of optical fibers may lead directly to the light source and processing circuitry 355 of the prior related patents with no intervening optical coupling and thereby minimize light loss. Alternatively, it is sometimes desirable that means be provided enabling the invention assembly 320 to be quickly optically coupled and uncoupled at the body. For this situation, quick connect-disconnect optical couples 352, 353 are provided.

Each socket 335, 336 is provided at the open base end with three radially extending thin, flexible tabs 339 preferably of uniform size and of uniform length T. A double-sided pressure sensitive tape 341 is secured to the bottom of each respective tab 339 and is used as a means of securing the respective socket 335 or 336 to the body surface. Removable covering strips may be employed to protect the adhesive material prior to installation. Additionally, as later referred to in connection with Figs. 29 and 30 it will be noted that the critical distance M between the light source module 350 and light detector module 360 can be established by overlapping a pair of tabs 339 and using the length T as a locating device as best illustrated in Fig. 29. Pad 330 is formed with two slits 331, 332 leading from socket holes 333, 334 and spaced apart by the same critical distance M. Distance M represents the same critical distance previously designated as distance S in Figs. 1 and 7. Thus, the space between the slits 331, 332 can also be used as a spacing reference. Slits 331, 332 also facilitate assembly of pad 330 on the respective sockets 335, 336 after the respective optical modules 350, 360 have been fully nested in their respective sockets 335, 336 by allowing the respective outgoing optical cables 351, 361 secured through the respective quick disconnect couplings 352, 353 to pass through slits 331, 332 and over pad 330 during assembly of pad 330 on sockets 335, 336.

While serving different functions, optical modules 350 and 360 are basically of similar size and construction and will be more fully described in reference to Figs. 16–21. Module 350, by way of example, comprises a hollow, circular-shaped housing 370 having a back cover plate 371 and a flat front face 372 formed with a central aperture 373. The fiber bundle 351 couples through quick disconnect optical coupling 352 and terminates with a right angle shaped terminal end 379 having a slightly protruding portion with a ground optical face 380 located in the aperture 373. The void within housing 370 surrounding the right angle shaped terminal end 379 is filled with an epoxy or similar hard-setting compound to facilitate securement of the terminal end 379 within housing 370 and back cover plate 371 is suitably glued or otherwise secured in place after such assembly.

Terminal end 379 of fiber bundle 351 provides both a near-infrared light source terminal and a corrective detector terminal with selected fibers being employed for bringing light to the point of light entry and other randomly dispersed selected fibers being employed for collecting light reflected back directly from or near (1–3 mms) the point of light entry. The manner in which such corrective and measured light sources operate is explained in the related prior patents.

Module 360, as previously stated, employs a similar construction to that of module 350 and mounts fiber bundle 361 connected through quick disconnect optical coupling 353 and having a right angle shaped terminal end 382 with a slightly protruding portion having a ground optical face 383. Bundle 361 is used as a means for collecting the measured reflected light for processing, as fully explained in the related prior patents. Further, during the light measuring operation, modules 350 and 360 are mounted in their respective module sockets 335, 336 and are positioned on the body so as to maintain uniform the spacing M within the limits discussed in the related prior patents.

Shielding of ambient light is deemed critically important especially when metabolic trends are being monitored and discrete changes are significant though small in value. Thus, when the respective modules 350, 360 have been assembled in the respective sockets 335, 336 and are mounted as depicted in Fig. 15 with pad 330 adhesively secured over the respective socket tabs 339, an additional protective shielding is provided by employing the auxiliary pad of light shielding material 340 which is provided with double-sided adhesive tape 344 such that pad 340 can be firmly secured and provide adequate light shielding over the respective modules 350, 360 assembled in their respective sockets 335, 336 as depicted in Fig. 15. The corresponding optical cables 351, 361 are led out under pad 340 and are preferably wrapped with a black felt strip 348 at the point where the cables exit from beneath pad 340 to provide additional shielding. A dense, black, highly flexible, hard neoprene rubber sheet of 1/64" thickness has been found suitable for use in making pad 340.

As another aspect of the present invention,

a pair of thin, double-sided, annular-shaped, pressure sensitive adhesive tapes 400, 401 are employed on the respective modules 350, 360 and are used to assist in providing the desired ambient light shielding around the respective optical faces 380, 383. Tapes 400, 401 are preformed in the shape illustrated in Fig. 14 and typically have removable adhesive protective covering which, after removal, allows the respective tapes 400, 401 to be attached on one side to the respective modules 350, 360 while leaving the opposite adhesive surfaced side of the respective tapes 400, 401 exposed for securing to the respective body surfaces opposite the respective optical faces 380, 383.

In using the invention assembly 320, an optical gel is applied to each optical face 380, 383 and the respective annular adhesive tapes 400, 401 are installed around the respective optical faces 380, 383. The respective modules 350, 360 are then snugly fitted into their respective sockets 335, 336. In order to obtain the desired spacing M between the light source module 350 and the light detector 360, the socket tabs 339 may be oriented prior to being adhered to the body surface as in Fig. 29 such that the socket tab length T maintains the correct distance M. In this mode of installation after the optical modules 350, 360 have been snugly fitted into their respective sockets 335, 336 as illustrated in Figs. 25–26 for module 360 as an example, the respective covers for adhesive strips 341 may be removed from the socket tabs 339 and from annular tabs 400, 401 and the modules 350, 360 adhered to the body in the orientation illustrated in Fig. 29. After this step, the adhesive cover for the adhesive on pad 330 is removed and pad 330 is next installed over the assembled optical modules 350, 360 and sockets 335, 336 utilizing the slits 331, 332 to position the optical cables 351, 361 extending out over pad 330 as seen in Figs. 15 and 30.

In another installation mode after the respective optical modules 350, 360 are snugly fitted into the respective sockets 335, 336 the sockets are installed in pad 330 as illustrated in Fig. 30. The spacing between the slits 331, 332 thus establishes the desired spacing M required during the measuring operation. In this mode of installation, the covers for the adhesive on adhesive tapes 341 on socket tabs 339, the covers on the adhesive on annular tapes 400, 401 and the cover for the adhesive on pad 330 may be removed after the respective sockets 335, 336 with the respective modules 350, 360 have been assembled in the manner of Fig. 30. The entire pad-socket-module assembly illustrated in Fig. 30 can then be adhered to the body utilizing the adhesive surfaces of the optical tapes 400, 401, the adhesive surfaces on the socket tabs 339 and the adhesive surface provided on the pad 330. The auxiliary pad 340 is then next installed in the manner previously described following which a suitable light shielding cape 345 is draped over the head and over those portions of the optical cabling proximate the assembly 320 to provide additional ambient light shielding.

From the foregoing description of the second embodiment of the invention, various advantages over the light source-detector mounting arrangements set forth in the prior patents will become evident. A major advantage resides in the ability to secure the assembly 320 to the body, particularly to the head for brain monitoring, without requiring the use of a strap as in the first embodiment. Thus, if it becomes necessary to tilt the head backward during the surgical or medical procedure, this can be accomplished with the structure of the second embodiment as illustrated in Fig. 15 without dislodging the monitoring assembly 320. Alternatively, when the head or other portion of the body being monitored is not required to be tilted, the described invention apparatus lends itself to this application mode as does the first embodiment.

The respective sockets 335, 336 may be made of a suitable plastic and thus may be formed as relatively inexpensive single end-use components. Additionally, pad 330 may also be a disposable single end-use component as well as the auxiliary pad 340. Thus, by being able to provide these operating components in a form adapted to disposable, single end-use, substantial expense is saved with regard to washing and sterilizing the invention apparatus following a surgical or medical procedure.

The invention apparatus also achieves a significant advance in light shielding in being able to utilize the combined shielding characteristics of the annular tapes 400, 401 which surround the respective optical faces 380, 383 on modules 350, 360 in conjunction with the shielding properties of pad 330 which can be tightly secured by means of the adhesive 338 on the surface of pad 330. Additional shielding is, of course, provided by the auxiliary shielding pad 340 utilizing the adhesive strips 344.

CLAIMS

1. In a spectrophotometric measuring apparatus for measuring in situ, in vivo, non-invasively, atraumatically, harmlessly, rapid and continuously a selected activity of a selected portion of the body where such activity bears a measurable relation to an absorption characteristic of the selected portion for a particular wavelength of light, said apparatus being of the type having:

(a) light source means including:

(i) a plurality of near-infrared light sources located external of the body and having light

emissions of different wavelengths in a selected spectral range and of an intensity below the level damaging to the body and said selected portion but sufficient to be detectable by a light sensor after transmission through an optical transmission-reflectance path including said selected portion thereof and extending between selected points of light entry and exit spaced several centimeters apart and located on contiguous skin surface areas of the body and after scattering in and reflectance from said selected portion along said path; and

(ii) means operatively associated with said light sources to produce emissions representing at least one measuring wavelength and at least one reference wavelength within said spectral range for transmission along said path to said selected portion, said measuring wavelength being selected such that said selected portion exhibits a selected absorption therefor, the extent of which is dependent upon the specific state of the activity being measured;

(b) first optical cable means providing a bundle of optical fibers with selected fibers connected for receiving and transmitting the output light emissions of said light sources at said measuring and reference wavelengths to a selected point of light entry proximate said body;

(c) second optical cable means providing a bundle of optical fibers connected for receiving deeply penetrating light emissions reflected and scattered to a selected said point of light exit from said selected portion of said body and transmitting such exiting light emissions to a processing means;

(d) processing means operatively associated with said light source means adapted to produce from the outputs of said first and second optical cable means an electrical output signal representing the difference in absorption of said measuring and reference wavelengths by said selected body portion as a function of the state of said activity and further adapted to convert said electrical output signal to a signal providing a substantially continuous and rapid measure of said activity;

the improvement comprising:

(e) a detachable, body mountable apparatus operatively associated with said light source, first and second optical cable and processing means comprising:

(i) a flexible, elongated support member adapted to be releasably secured to the body proximate a said selected portion of the body having a selected set of said spaced light entry and exit points, to provide ambient light shielding over said light entry and exit points and to conform to the curvature and shape of the body at the location thereof;

(ii) module mounting structure adapted to be light shielded and held by said support member against said selected portion of the body and to deform in shape in correspondence with the curvature assumed by said support member when secured to the body;

(iii) a first preformed optical module mounted in said structure and providing a hollow housing enclosing first light guide means formed by a bundle of optical fibers optically coupled to said first optical cable means and having a first optical light emitting face centrally positioned in an outer face of said housing and adapted to be mated in a substantially pressed fit relation with said selected point of light entry utilizing selected fibers of said bundle for entry of light in selected wavelengths to be transmitted, deeply reflected and scattered along said path and to said selected portion of the body; and

(iv) a second preformed optical module mounted in said structure and providing a second hollow housing enclosing second light guide means formed by a bundle of optical fibers optically coupled to said second optical cable means and having a second optical light receiving face centrally positioned in an outer face of said second module housing and adapted to be mated in a substantially pressed fit relation with said selected point of light exit spaced said several centimeters from said point of light entry for receiving and transmitting deeply penetrating light emissions reflected and scattered to said selected point of light exit from said selected portion of said body.

2. In an apparatus as claimed in claim 1 wherein each said optical module includes openings in the respective outer faces of the respective housings thereof surrounding the respective optical faces thereof and means communicating said openings to a vacuum source whereby securement of said optical faces to the respective points of light entry and exit is enhanced by a vacuum assisted pull on the skin surrounding said points.

3. In an apparatus as claimed in claim 1 wherein said module mounting structure is detachably secured to said support member.

4. In a spectrophotometric measuring apparatus as claimed in claim 1 wherein:

(a) said module mounting structure comprises:

first and second socket structures, each providing a hollow wall structure having an open base end and flexible tab members extending radially outward from said base end, said first socket structure being adapted to receive in snug fit relation said first optical module housing with an external optical cable connected portion of the fiber bundle associated with said first optical module leading from the wall of said first socket structure and the said second socket structure being adapted to receive in sung-fit relation said second optical module with an external optical cable connected portion of the fiber bundle associated therewith leading from the wall of said second socket structure, and including adhesive

means on the bottom surfaces of said tab members enabling said tab members to be secured to the body in laterally spaced relation whereby to secure said optical modules in the same spaced relation; and

(b) wherein said elongated flexible support member comprises:

a flexible light shielding pad having one adhesive surfaced side and being adapted to be fitted over said socket structures with said modules fitted therein and in a manner enabling said adhesive surfaced side to be adhesively secured to the body and in a manner enabling said tab members to be covered and the respective optical faces of said modules to be light shielded by said adhesively faced side of said panel with the respective optical cabling connected to said modules overlying the opposite side of said pad.

5. In a spectrophotometric measuring apparatus as claimed in claim 1 including at least one auxiliary ambient light-shielding cover adapted to overlie said support member during operation of said apparatus.

6. In a spectrophotometric measuring apparatus as claimed in claim 1 wherein:

(a) said first optical cable means bundle of optical fibers including other selected fibers connected for transmitting deeply penetrating light emissions reflected directly back from any skin, bone and tissue at or within a few millimeters of said selected point of light entry to a processing means;

(b) said processing means electrical output signal is corrected for changes in blood volume of said skin, bone and tissue during the measuring cycle; and

(c) said first preformed optical module bundle of optical fibers include other selected fibers of said bundle for receiving light emissions reflected directly back from any skin, bone and tissue at or within a few millimeters of said selected point of light entry.

7. In a spectrophotometric measuring apparatus as claimed in claim 4 wherein said shielding pad comprises a flexible light shielding pad having a pair of apertures formed to receive said socket structures in a predetermined spaced relation and with slit portions of said pad connecting said apertures to an outer edge thereof thereby enabling said shielding pad to be fitted over said tab members while allowing the optical cables associated with said modules to lead away from said shielding pad over and above the outer surface thereof.

8. In a spectophotometric measuring apparatus as claimed in claim 4 including at least one auxiliary ambient light-shielding cover adapted to overlie said first shielding pad during operation of said apparatus.

9. In a spectrophotometric measuring apparatus as claimed in claim 4 wherein said first and second optical module housings are of similar size and cylindrical shape, and socket hollow wall structures are of similar size and cylindrical shape so as to provide hollow cylindrical receptacles mating in a snug fit said optical module housings and wherein said socket hollow wall structures are slotted for passing therethrough the respective fiber bundles leading from the respective said modules and each said socket hollow wall structure has a closed end wall opposite the base end thereof.

10. A spectrophotometric measuring apparatus substantially as herein described with reference to the accompanying drawings.

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